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Patent Application

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of

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for

DISEASE SIMULATION SYSTEM AND METHOD

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CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation copending patent
application 08/781,278 filed January 10, 1997, which is
20 herein incorporated by reference.

BACKGROUND -- FIELD OF THE INVENTION

The present invention relates generally to disease simulation
25 systems, and in particular to a system and method for
simulating a disease control parameter and for predicting the
effect of patient self-care actions on the disease control
parameter.

BACKGROUND -- DESCRIPTION OF PRIOR ART
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Managing a chronic disease or ongoing health condition
requires the monitoring and controlling of a physical or
mental parameter of the disease. Examples of these disease
35 control parameters include blood glucose in diabetes,
respiratory flow in asthma, blood pressure in hypertension,
cholesterol in cardiovascular disease, weight in eating
disorders, T-cell or viral count in HIV, and frequency or
timing of episodes in mental health disorders. Because of

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5 the continuous nature of these diseases, their corresponding control parameters must be monitored and controlled on a regular basis by the patients themselves outside of a medical clinic.

10 Typically, the patients monitor and control these parameters in clinician assisted self-care or outpatient treatment programs. In these treatment programs, patients are responsible for performing self-care actions which impact the control parameter. Patients are also responsible for
15 measuring the control parameter to determine the success of the self-care actions and the need for further adjustments. The successful implementation of such a treatment program requires a high degree of motivation, training, and understanding on the part of the patients to select and
20 perform the appropriate self-care actions.

One method of training patients involves demonstrating the effect of various self-care actions on the disease control parameter through computerized simulations. Several computer
25 simulation programs have been developed specifically for diabetes patients. Examples of such simulation programs include *BG Pilot* ™ commercially available from Raya Systems, Inc. of 2570 El Camino Real, Suite 520, Mountain View, CA. 94040 and *AIDA* freely available on the World Wide Web at the
30 Diabetes UK website http://www.pcug.co.uk/diabetes/aida.htm.

Both *BG Pilot* ™ and *AIDA* use mathematical compartmental models of metabolism to attempt to mimic various processes of a patient's physiology. For example, insulin absorption
35 through a patient's fatty tissue into the patient's blood is represented as a flow through several compartments with each compartment having a different flow constant. Food absorption from mouth to stomach and gut is modeled in a similar manner. Each mathematical compartmental model uses

5   partial differential equations and calculus to simulate a
physiological process.

This compartmental modeling approach to disease simulation
has several disadvantages. First, understanding the
10   compartmental models requires advanced mathematical knowledge
of partial differential equations and calculus which is far
beyond the comprehension level of a typical patient.
Consequently, each model is an unfathomable "black box" to
the patient who must nevertheless trust the model and rely
15   upon it to learn critical health issues.

A second disadvantage of the compartmental modeling approach
is that a new model is needed for each new disease to be
simulated. Many diseases involve physiological processes for
20   which accurate models have not been developed. Consequently,
the mathematical modeling approach used in *BG Pilot* ™ and
AIDA is not sufficiently general to extend simulations to
diseases other than diabetes.

25   A further disadvantage of the modeling approach used in *BG
Pilot* ™ and *AIDA* is that the mathematical models are not
easily customized to an individual patient. As a result, *BG
Pilot* ™ and *AIDA* are limited to simulating the effect of
changes in insulin and diet on the blood glucose profile of a
30   typical patient. Neither of these simulation programs may be
customized to predict the effect of changes in insulin and
diet on the blood glucose profile of an individual patient.

OBJECTS AND ADVANTAGES OF THE INVENTION

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In view of the above, it is an object of the present
invention to provide a disease simulation system which is
sufficiently accurate to teach a patient appropriate self-
care actions and sufficiently simple to be understood by the

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5   average patient. It is another object of the invention to
provide a disease simulation system which may be used to
simulate many different types of diseases. A further object
of the invention is to provide a disease simulation system
which may be easily customized to an individual patient.

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These and other objects and advantages will become more
apparent after consideration of the ensuing description and
the accompanying drawings.

15   SUMMARY OF THE INVENTION

The invention presents a system and method for simulating a
disease control parameter and for predicting the effect of
patient self-care actions on the disease control parameter.
20 According to the method, a future disease control parameter
value $X(t_j)$ at time t_j is determined from a prior disease
control parameter value $X(t_i)$ at time t_i based on an optimal
control parameter value $R(t_j)$ at time t_j, the difference
between the prior disease control parameter value $X(t_i)$ and
25 an optimal control parameter value $R(t_i)$ at time t_i, and a set
of differentials between patient self-care parameters having
patient self-care values $S_M(t_i)$ at time t_i and optimal self-
care parameters having optimal self-care values $O_M(t_i)$ at time
t_i. In the preferred embodiment, the differentials are
30 multiplied by corresponding scaling factors K_M and the future
disease control parameter value $X(t_j)$ is calculated according
to the equation:

$$X(t_j) = R(t_j) + (X(t_i)-R(t_i)) + \sum_M K_M(S_M(t_i)-O_M(t_i)).$$

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A preferred system for implementing the method includes an
input device for entering the patient self-care values $S_M(t_i)$.
The system also includes a memory for storing the optimal
control parameter values $R(t_i)$ and $R(t_j)$, the prior disease

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5   control parameter value $X(t_i)$, the optimal self-care values
$O_M(t_i)$, and the scaling factors K_M. A processor in
communication with the input device and memory calculates the
future disease control parameter value $X(t_j)$. A display is
connected to the processor to display the future disease
10   control parameter value $X(t_j)$ to a patient.

In the preferred embodiment, the system further includes a
recording device in communication with the processor for
recording an actual control parameter value $A(t_i)$ at time t_i,
15   an actual control parameter value $A(t_j)$ at time t_j, and actual
self-care parameters having actual self-care values $C_M(t_i)$ at
time t_i. The processor adjusts the scaling factors K_M based
on the difference between the actual control parameter value
$A(t_j)$ and the optimal control parameter value $R(t_j)$, the
20   difference between the actual control parameter value $A(t_i)$
and the optimal control parameter value $R(t_i)$, and the
difference between the actual self-care values $C_M(t_i)$ and the
optimal self-care values $O_M(t_i)$. Thus, the scaling factors K_M
are customized to an individual patient to predict the effect
25   on the disease control parameter of self-care actions
performed by the individual patient.

BRIEF DESCRIPTION OF THE DRAWINGS

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FIG. 1   is a schematic diagram of a simulation system
             according to the invention.
FIG. 2   is a sample physiological parameter entry screen
             according to the invention.
35   FIG. 3   is a sample self-care parameter entry screen
             according to the invention.
FIG. 4   is a table of values according to the invention.
FIG. 5   is a sample graph of disease control parameter
             values created from the table of FIG. 4.

25   DESCRIPTION

    The present invention is a system and method for simulating a
    disease control parameter and for predicting an effect of
    patient self-care actions on the disease control parameter.
30 In the following detailed description, numerous specific
    details are set forth in order to provide a thorough
    understanding of the present invention. However, it will be
    apparent to one of ordinary skill in the art that these
    specific details need not be used to practice the invention.
35 In other instances, well known structures, interfaces, and
    processes are not shown in detail to avoid unnecessarily
    obscuring the present invention.

5   FIGS. 1 - 10 illustrate a preferred embodiment of a simulation system according to the invention. The following table illustrates a representative sampling of the types of diseases, patient self-care parameters, and disease control parameters which may be simulated using the system and method
10 of the invention.

Disease	Self-Care Parameters	Control Parameter
Diabetes	insulin, diet, exercise	blood glucose level
Asthma	allergens, exercise, inhaled bronchial dilators, anti-inflammatory medications	peak flow rate
Obesity	diet, exercise, metabolism altering medications	weight
Hypertension	diet, exercise, stress reduction, blood pressure medications	blood pressure
Coronary Artery Disease	diet, exercise, stress reduction, lipid lowering medications	cholesterol
Panic Disorder	stress reduction, anti-depressant medications	number of episodes
Nicotine Addiction	cigarettes smoked, coping behaviors	urges to smoke

The above table is not intended as an exhaustive list, but merely as a representative sampling of the types of diseases
15 and disease control parameters which may be simulated. For simplicity, the preferred embodiment is described with reference to a single disease, diabetes, having a single disease control parameter, a blood glucose level. However, it is to be understood that the system and method of the
20 invention are sufficiently flexible to simulate any disease which has a measurable control parameter and which requires patient self-care actions.

Referring to FIG. 1, a simulation system generally indicated
25 at 10 includes a server 12 having a processor and memory for executing a simulation program which will be described in detail below. Server 12 is in communication with a healthcare provider computer 14 through a network link 48.

5   Healthcare provider computer **14** is preferably a personal
computer located at a healthcare provider site, such as a
doctor's office.

Server **12** is also in communication with a patient multi-media
10   processor **24** through a network link **50**. Patient multi-media
processor **24** is located at a patient site, typically the
patient's home. In the preferred embodiment, server **12** is a
world wide web server, multi-media processor **24** is a web TV
processor for accessing the simulation program on server **12**,
15   and links **48** and **50** are Internet links. Specific techniques
for establishing client/server computer systems in this
manner are well known in the art.

Healthcare provider computer **14** includes a processor and
20   memory, a standard display **16**, and a keyboard **20**. Computer
14 further includes a card slot **18** for receiving a data
storage card, such as a smart card **22**. Computer **14** is
designed to read data from card **22** and write data to card **22**.
Patient multi-media processor **24** includes a corresponding
25   card slot **26** for receiving card **22**. Processor **24** is
designed to read data from card **22** and write data to card **22**.
Thus, healthcare provider computer **14** communicates with
patient multi-media processor **24** via smart card **22**. Such
smart card data communication systems are also well known in
30   the art.

Multi-media processor **24** is connected to a display unit **28**,
such as a television, by a standard connection cord **32**.
Display unit **28** has a screen **30** for displaying simulations to
35   the patient. An input device **34**, preferably a conventional
hand-held remote control unit or keyboard, is in signal
communication with processor **24**. Device **34** has buttons or
keys **36** for entering data in processor **24**.

5   System **10** also includes an electronic recording device **38** for recording actual control parameter values and patient self-care data indicating actual self-care actions performed by the patient. Recording device **38** includes a measuring device **40** for producing measurements of the disease control

10   parameter, a keypad **44** for entering the self-care data, and a display **42** for displaying the control parameter values and self-care data to the patient.

Recording device **38** is preferably portable so that the

15   patient may carry device **38** and enter the self-care data at regular monitoring intervals. Device **38** is further connectable to healthcare provider computer **14** via a standard connection cord **46** so that the control parameter values and patient self-care data may be uploaded from device **38** to

20   computer **14**. Such recording devices for producing measurements of a disease control parameter and for recording self-care data are well known in the art. For example, U.S. Patent 5,019,974 issued to Beckers on May 28, 1991 discloses such a recording device.

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In the example of the preferred embodiment, the disease control parameter is the patient's blood glucose level and recording device **38** is a blood glucose meter, as shown in FIG. 10. In this embodiment, measuring device **40** is a blood

30   glucose test strip designed to test blood received from a patient's finger **54**. Device **38** is also designed to record values of the patient's diet, medications, and exercise durations entered by the patient through keypad **44**. Of course, in alternative embodiments, the recording device may

35   be a peak flow meter for recording a peak flow rate, a cholesterol meter for recording a cholesterol level, etc.

The simulation system of the present invention includes a simulation program which uses a mathematical model to

5   calculate disease control parameter values. The following
variables used in the mathematical model are defined as
follows:

N = Normal time interval in which patient self-care actions
10   are employed to make a measurable difference in the
disease control parameter or a natural rhythm occurs in
the disease control parameter. For diabetes and asthma,
time interval N is preferably twenty-four hours. For
obesity or coronary artery disease, time interval N is
15   typically three to seven days.

t_1, t_2,...t_i, t_j...t_N = Time points at which the disease
control parameter is measured by a patient. For a daily
rhythm control parameter such as a blood glucose level,
20   the time points are preferably before and after meals.
For weight or cholesterol control parameters, the time
points are preferably once a day or once every second
day.

25   $X(t)$ = Simulated disease control parameter value at time t
determined by the simulation program.

$R(t)$ = Optimal control parameter value at time t expected as
a normal rhythm value of the disease control parameter
30   at time t if the patient performs optimal self-care
actions in perfect compliance from time t_1 to the time
point immediately preceding time t.

$A(t)$ = actual control parameter value at time t measured by
35   the patient.

$O_M(t_i)$ = Optimal self-care parameter values $O_1(t_i)$, $O_2(t_i)$,
...$O_m(t_i)$ at time t_i expected to produce optimal
control parameter value $R(t_j)$ at time t_j. For

5   example, a diabetes patient's optimal self-care
parameter values include a prescribed dose of insulin,
a prescribed intake of carbohydrates, and a prescribed
exercise duration.

10   $S_M(t_i)$ = Patient self-care parameter values $S_1(t_i)$, $S_2(t_i)$,
...$S_m(t_i)$ at time t_i entered in the simulation system
by the patient to simulate self-care actions.

$C_M(t_i)$ = Actual self-care parameter values $C_1(t_i)$, $C_2(t_i)$,
15   ...$C_m(t_i)$ at time t_i indicating actual self-care
actions performed by the patient at time t_i.

K_M = Corresponding scaling factors $K_1(t_i)$, $K_2(t_i)$, ...K_m for
weighting the impact on a future disease control
20   parameter value $X(t_j)$ at time t_j which results from
differentials between patient self-care values $S_M(t_i)$
and corresponding optimal self-care values $O_M(t_i)$.

With these definitions, future disease control parameter
25   value $X(t_j)$ is calculated according to the equation:

$$X(t_j) = R(t_j) + (X(t_i) - R(t_i)) + \sum_M K_M(S_M(t_i) - O_M(t_i)).$$

Future disease control parameter value $X(t_j)$ at time t_j is
30   determined from a prior disease control parameter value $X(t_i)$
at time t_i based on an optimal control parameter value $R(t_j)$
at time t_j, the difference between prior disease control
parameter value $X(t_i)$ and an optimal control parameter value
$R(t_i)$ at time t_i, and a set of differentials between patient
35   self-care values $S_M(t_i)$ and optimal self-care values $O_M(t_i)$.
The differentials are multiplied by corresponding scaling
factors K_M.

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5   Thus, as patient self-care parameter values $S_M(t_i)$ deviate
     from optimal self-care parameter values $O_M(t_i)$, future
     disease control parameter value $X(t_j)$ deviates from optimal
     control parameter value $R(t_j)$ by an amount proportional to
     scaling factors K_M. This mathematical model follows the
10   patient's own intuition and understanding that if the patient
     performs optimal self-care actions in perfect compliance, the
     patient will achieve the optimal control parameter value at
     the next measurement time. However, if the patient deviates
     from the optimal self-care actions, the disease control
15   parameter value will deviate from the optimal value at the
     next measurement time.

     The simulation program is also designed to generate an entry
     screen for entry of the patient self-care parameter values.
20   FIG. 3 shows a sample patient self-care parameters entry
     screen **52** as it appears on display unit **28**. The patient
     self-care parameters include a food exchange parameter
     expressed in grams of carbohydrates consumed, an insulin dose
     parameter expressed in units of insulin injected, and an
25   exercise duration parameter expressed in fifteen minute units
     of exercise performed.

     These self-care parameters are illustrative of the preferred
     embodiment and are not intended to limit the scope of the
30   invention. It is obvious that many different self-care
     parameters may be used in alternative embodiments. Screen **52**
     contains data fields **53** for entering a food exchange
     parameter value $S_1(t)$, an insulin dose parameter value
     $S_2(t)$, and an exercise duration parameter value $S_3(t)$. Each
35   data field **53** has a corresponding time field **51** for entering
     a time point corresponding to the patient self-care parameter
     value. Screen **52** also includes an OK button **55** and a cancel
     button **57** for confirming and canceling, respectively, the
     values entered in screen **52**.

FIG. 4 shows a sample table of values **56** created by the simulation program using the data entered by the patient through the self-care parameters entry screen. Table **56** includes a column of simulated disease control parameter values calculated by the simulation program, as will be explained in the operation section below. The simulation program is further designed to generate graphs of simulated disease control parameter values. FIG. 5 illustrates a sample graph **58** generated from table **56** as it appears on screen **30** of the display unit. Specific techniques for writing a simulation program to produce such a graph are well known in the art.

In the preferred embodiment, healthcare provider computer **14** is programmed to determine scaling factors K_M from values of physiological parameters of the patient. FIG. 2 shows a sample physiological parameter entry screen **41** as it appears on the healthcare provider computer. The physiological parameters of the patient include a body mass, a metabolism rate, a fitness level, and hepatic and peripheral insulin sensitivities. These physiological parameters are illustrative of the preferred embodiment and are not intended to limit the scope of the invention. It is obvious that many different physiological parameters may be used in alternative embodiments. Screen **41** includes data fields **43** for entering physiological parameter values, an OK button **45** for confirming the values, and a cancel button **47** for canceling the values.

Healthcare provider computer **14** stores indexes for determining the scaling factors from the physiological parameters entered. For example, FIG. 4 shows an insulin sensitivity scaling factor K_2 corresponding to insulin dose parameter value $S_2(t)$. Computer **14** is programmed to

5   determine from a stored insulin index a value of scaling

factor K_2 based on the entered values of the patient's body

mass and insulin sensitivities. In this example, computer **14**

determines a value of -40 for scaling factor K_2, indicating

that for this patient, one unit of insulin is expected to

10   lower the patient's blood glucose level by 40 mg/dL.

Computer **14** is programmed to determine the remaining scaling

factors in a similar manner. The specific indexes required

to determine the scaling factors from values of a patient's

physiological parameters are well known in the art.

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In the preferred embodiment, healthcare provider computer **14**

is also programmed to adjust scaling factors K_M based on the

difference between an actual control parameter value $A(t_j)$

measured at time t_j and optimal control parameter value

20     $R(t_j)$, the difference between an actual control parameter

value $A(t_i)$ measured at time t_i and optimal control parameter

value $R(t_i)$, and the difference between actual self-care

values $C_M(t_i)$ performed by the patient at time t_i and optimal

self-care values $O_M(t_i)$.

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Scaling factors K_M are adjusted to fit the mathematical model

presented above, preferably using a least squares, chi-

squares, or similar regressive fitting technique. Specific

techniques for adjusting coefficients in a mathematical model

30   are well known in the art. For example, a discussion of

these techniques is found in "Numerical Recipes in C: The Art

of Scientific Computing", Cambridge University Press, 1988.

The operation of the preferred embodiment is illustrated in

35   FIG. 13. FIG. 13 is a flow chart illustrating a preferred

method of using system **10** to simulate the disease control

parameter. In step **200**, optimal self-care values and optimal

control parameter values for each time point are determined

for the patient, preferably by the patient's healthcare

5   provider. The optimal self-care values and optimal control parameter values are then entered and stored in provider computer **14**.

In the preferred embodiment, the optimal self-care values

10   include an optimal food exchange parameter value $O_1(t)$ expressed in grams of carbohydrates, an optimal insulin dose parameter value $O_2(t)$ expressed in units of insulin, and an optimal exercise duration parameter value $O_3(t)$ expressed in fifteen minute units of exercise. Specific techniques for

15   prescribing optimal self-care values and optimal control parameter values for a patient are well known in the medical field.

In step **202**, the healthcare provider determines the

20   physiological parameter values of the patient and enters the physiological parameter values in computer **14** through entry screen **41**. As shown in FIG. 2, the physiological parameter values include a body mass, a metabolism rate, a fitness level, and hepatic and peripheral insulin sensitivities.

25   Specific techniques for testing a patient to determine these physiological parameter values are also well known in the medical field.

Following entry of the physiological parameter values,

30   computer **14** determines scaling factors K_M from the stored indexes, step **204**. For example, FIG. 4 shows a food exchange scaling factor K_1 corresponding to food exchange parameter value $S_1(t)$, an insulin sensitivity scaling factor K_2 corresponding to insulin dose parameter value $S_2(t)$, and an

35   exercise duration scaling factor K_3 corresponding to exercise duration parameter value $S_3(t)$.

In this example, computer **14** determines a value of 4 for scaling factor K_1, a value of -40 for scaling factor K_2, and

5   a value of -5 for scaling factor K_3. These values indicate
     that one gram of carbohydrate is expected to raise the
     patient's blood glucose level by 4 mg/dL, one unit of insulin
     is expected to lower the patient's blood glucose level by 40
     mg/dL, and fifteen minutes of exercise is expected to lower
10   the patient's blood glucose level by 5 mg/dL. Of course,
     these values are just examples of possible scaling factors
     for one particular patient. The values of the scaling
     factors vary between patients in dependence upon the
     physiological parameter values determined for the patient.
15

     The determined optimal self-care values, optimal control
     parameter values, and scaling factors are then stored on
     smart card **22**, step **206**. Typically, the values are stored on
     smart card **22** during a patient visit to the healthcare
20   provider. The patient then takes home smart card **22** and
     inserts smart card **22** in patient multi-media processor **24**,
     step **208**. Next, the patient accesses the simulation program
     on server **12** through multi-media processor **24**, step **210**.

25   The simulation program generates self-care parameters entry
     screen **52**, which is displayed to the patient on screen **30** of
     display unit **28**. In step **212**, the patient enters patient
     self-care values $S_M(t)$ and corresponding time points in data
     fields **53** and **51**, respectively, using input device **34**. The
30   optimal self-care values, optimal control parameter values,
     scaling factors, and patient self-care values are transmitted
     from multi-media processor **24** to server **12** through link **50**.
     In step **214**, the simulation program calculates simulated
     disease control parameter values at each time point according
35   to the equation:

$$X(t_j) = R(t_j) + (X(t_i) - R(t_i)) + \sum_M K_M(S_M(t_i) - O_M(t_i))$$

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5   Thus, each future disease control parameter value $X(t_j)$ is calculated from optimal control parameter value $R(t_j)$, the difference between prior disease control parameter value $X(t_i)$ and optimal control parameter value $R(t_i)$, and the set of differentials between patient self-care values $S_M(t_i)$ and

10 optimal self-care values $O_M(t_i)$. The differentials are multiplied by corresponding scaling factors K_M. In the preferred embodiment, first simulated disease control parameter value $X(t_1)$ at time t_1 is set equal to first optimal control parameter value $R(t_1)$ at time t_1. In an

15 alternative embodiment, first simulated disease control parameter value $X(t_1)$ is determined from the last disease control parameter value calculated in a prior simulation.

FIGS. 4 - 5 illustrate a first example of simulated disease

20 control parameter values calculated by the simulation program. Referring to FIG. 4, the simulation program creates table of values **56** having a time column, an optimal control parameter value column, a simulated control parameter value column, three self-care value differential columns indicating

25 differentials between patient self-care parameter values and optimal self-care parameter values, and three corresponding scaling factor columns for weighting the corresponding self-care value differentials.

30 Table **56** illustrates the simplest simulation, in which the patient follows the optimal self-care actions in perfect compliance at each time point. In this simulation, each patient self-care parameter value equals its corresponding optimal self-care parameter value, so that the simulated

35 disease control parameter value at each time point is simply equal to the optimal control parameter value at each time point. Referring to FIG. 5, the simulation program generates graph **58** of the simulated disease control parameter values.

5   Graph **58** is displayed to the patient on screen **30** of display
unit **28**, step **216**.

FIGS. 6 - 7 illustrate a second example of simulated disease
control parameter values calculated by the simulation

10   program. FIG. 6 shows a table of values **59** having identical
structure to table **56**. Table **59** illustrates a simulation in
which the patient consumes 10 extra grams of carbohydrates at
8:00 and exercises for 60 extra minutes at 15:00. In this
simulation, the differential $S_1(t) - O_1(t)$ is equal to 10 at

15   8:00 due to the 10-extra grams of carbohydrates consumed by
the patient. Because scaling factor K_1 equals 4, the
simulation program calculates simulated disease control
parameter value $X(t_2)$ at time point 10:00 as 40 mg/dL higher
than optimal control parameter value $R(t_2)$ at 10:00.

20

Similarly, the differential $S_3(t) - O_3(t)$ is equal to 4 at
time point 15:00 due to the 60 extra minutes of exercise
performed by the patient. With simulated disease control
parameter value $X(t_4)$ exceeding optimal control parameter

25   value $R(t_4)$ by 40 mg/dL at 15:00 and with scaling factor K_3
equal to -5, the simulation program calculates simulated
disease control parameter value $X(t_5)$ at time point 18:00 as
20 mg/dL higher than optimal control parameter value $R(t_5)$.
FIG. 7 shows a graph **60** of the simulated disease control

30   parameter values determined in table **59**. Graph **60** is
displayed to the patient on screen **30** of the display unit.

FIGS. 8 - 9 illustrate a third example of simulated disease
control parameter values calculated by the simulation

35   program. Referring to FIG. 8, a table of values **61**
illustrates a simulation in which the patient consumes 10
extra grams of carbohydrates at 8:00, injects 1 extra unit of
insulin at 10:00, and exercises for 60 extra minutes at
15:00. The differential $S_2(t) - O_2(t)$ is equal to 1 at

5   10:00 due to the 1 extra unit of insulin injected by the
     patient. With simulated disease control parameter value
     $X(t_2)$ exceeding optimal control parameter value $R(t_2)$ by 40
     mg/dL at 10:00, and with scaling factor K_2 equal to -40, the
     simulation program calculates simulated disease control
10   parameter value $X(t_3)$ at time point 12:00 as equal to optimal
     control parameter value $R(t_3)$. FIG. 8 shows a graph **62** of
     the simulated disease control parameter values determined in
     table **61**.

15   In addition to performing simulations with the simulation
     program, the patient records actual control parameter values
     and actual self-care values indicating actual self-care
     actions performed by the patient at each time point, step
     218. These values are preferably recorded in recording
20   device **38**. Upon the patient's next visit to the healthcare
     provider, the actual control parameter values and actual
     self-care values are uploaded to provider computer **14**, step
     220. Those skilled in the art will appreciate that recording
     device **38** may also be networked to provider computer **14**
25   through a modem and telephone lines or similar network
     connection. In this alternative embodiment, the actual
     control parameter values and actual self-care values are
     transmitted directly from the patient's home to provider
     computer **14**.
30
     In step **222**, provider computer **14** adjusts scaling factors K_M
     based on the difference between the actual control parameter
     values and the optimal control parameter values at each time
     point and the difference between the actual self-care values
35   and the optimal self-care values at each time point. Scaling
     factors K_M are adjusted to fit them to the actual patient
     data recorded. In this manner, the scaling factors are
     customized to the individual patient to enable the patient to
     run customized simulations. The new values of the scaling

5   factors are stored on smart card **22** which the patient takes
home and inserts in processor **24** to run new simulations.

FIGS. 11 - 12 illustrate a second embodiment of the
invention. The second embodiment differs from the preferred
10   embodiment in that the components of the simulation system
are contained in a single stand-alone computing device **64**.
The second embodiment also differs from the preferred
embodiment in that the system predicts each future disease
control parameter value from an actual measured disease
15   control parameter value rather than from a prior simulated
disease control parameter value.

Referring to FIG 11, computing device **64** includes a housing
66 for holding the components of device **64**. Housing **66** is
20   sufficiently compact to enable device **64** to be hand-held and
carried by a patient. Device **64** also includes measuring
device **40** for producing measurements of actual control
parameters values and a display **70** for displaying data to the
patient. Device **64** further includes a keypad **68** for entering
25   in device **64** the optimal control parameter values, the
optimal self-care values, the patient self-care parameter
values, the actual self-care parameter values, and the
patient's physiological parameter values.

30   FIG. 12 shows a schematic block diagram of the components of
device **64** and their interconnections. Device **64** has a
microprocessor **72** and a memory **74** operably connected to
microprocessor **72**. Measuring device **40** and display **70** are
also connected to microprocessor **72**. Keypad **68** is connected
35   to microprocessor **72** through a standard keypad decoder **78**.
Microprocessor **72** is connected to an input/output port **76** for
entering in device **64** a simulation program to be executed by
microprocessor **72** which will be explained in detail below.

5   Memory **74** stores the optimal control parameter values, the optimal self-care values, the patient self-care parameter values, the actual self-care parameter values $C_M(t)$, the scaling factors, and the patient's physiological parameter values. Memory **74** also stores the simulation program to be
10   executed by microprocessor **72** and the indexes for calculating the scaling factors from the patient's physiological parameter values.

In the second embodiment, microprocessor **72** is programmed to
15   perform the functions performed by the healthcare provider computer of the preferred embodiment. The functions include determining scaling factors K_M from the patient's physiological parameter values. The functions also include adjusting scaling factors K_M based on the difference between
20   actual control parameter value $A(t_j)$ and optimal control parameter value $R(t_j)$, the difference between actual control parameter value $A(t_i)$ and optimal control parameter value $R(t_i)$, and the difference between actual self-care values $C_M(t_i)$ and optimal self-care values $O_M(t_i)$.

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The operation of the second embodiment is shown in FIG. 14. FIG. 14 is a flow chart illustrating a preferred method of using the system of the second embodiment to predict an effect of patient self-care actions on a disease control
30   parameter. In step **300**, the optimal control parameter values and optimal self-care values are entered in device **64** and stored in memory **74**. The optimal control parameter values and optimal self-care values may be entered in device **64** either through keypad **68** or through input/output port **76**.

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In step **302**, the patient or healthcare provider determines the patient's physiological parameter values. The physiological parameter values are then entered in device **64** through keypad **68** and stored in memory **74**. Following entry

5   of the physiological parameter values, microprocessor **72** determines scaling factors K_M from the indexes stored in memory **74**, step **304**. Scaling factors K_M are then stored in memory **74**. In an alternative method of determining and storing scaling factors K_M in memory **74**, scaling factors K_M

10   are determined in a healthcare provider computer, as previously described in the preferred embodiment. Scaling factors K_M are then entered in device **64** through keypad **68** or port **76** and stored in memory **74**.

15   In step **306**, the patient enters in microprocessor **72** actual disease control parameter $A(t_i)$. To enter actual disease control parameter $A(t_i)$, the patient places his or her finger on measurement device **40** at time t_i. Measurement device **40** produces a measurement of actual disease control parameter

20     $A(t_i)$ which is stored in memory **74**. In step **308**, the patient enters in microprocessor **72** patient self-care values $S_M(t_i)$ using keypad **68**. In step **310**, microprocessor **72** executes the simulation program stored in memory **74** to calculate future disease control parameter value $X(t_j)$.

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The simulation program of the second embodiment differs from the simulation program of the preferred embodiment in that future disease control parameter value $X(t_j)$ is calculated from actual disease control parameter $A(t_i)$ rather than from

30   a prior simulated disease control parameter value. In the second embodiment, future disease control parameter value $X(t_j)$ is calculated according to the equation:

$$X(t_j) = R(t_j) + (A(t_i) - R(t_i)) + \sum_M K_M(S_M(t_i) - O_M(t_i))$$

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Thus, future disease control parameter value $X(t_j)$ is determined from optimal control parameter value $R(t_j)$, the difference between actual disease control parameter $A(t_i)$ and optimal control parameter value $R(t_i)$, and the set of

differentials between patient self-care values $S_M(t_i)$ and optimal self-care values $O_M(t_i)$. The differentials are multiplied by corresponding scaling factors K_M. Future disease control parameter value $X(t_j)$ is displayed to the patient on display **70**, step **312**.

Once future disease control parameter value $X(t_j)$ is displayed to the patient, the patient uses the value to select appropriate actual self-care actions to perform at time t_i. Alternatively, the patient may perform several more simulations of future disease control parameter value $X(t_j)$ to decide appropriate self-care actions to perform at time t_i. Once the patient has performed the self-care actions, the patient enters in microprocessor **72** actual self-care values $C_M(t_i)$ indicating the self-care actions performed, step **314**. The actual self-care values are then stored in memory **74**.

The patient also enters in microprocessor **72** actual disease control parameter $A(t_j)$ measured at time t_j. To enter actual disease control parameter $A(t_j)$, the patient places his or her finger on measurement device **40** at time t_j. Measurement device **40** produces a measurement of actual disease control parameter $A(t_j)$ which is stored in memory **74**, step **316**. In step **318**, microprocessor **72** adjusts scaling factors K_M based on the difference between actual control parameter value $A(t_j)$ and optimal control parameter value $R(t_j)$, the difference between actual control parameter value $A(t_i)$ and optimal control parameter value $R(t_i)$, and the difference between actual self-care values $C_M(t_i)$ and optimal self-care values $O_M(t_i)$. In this manner, the scaling factors are customized to the individual patient to enable the patient to run customized simulations. The new values of the scaling factors are stored in memory **74** and used by microprocessor **72** in subsequent simulations.

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SUMMARY, RAMIFICATIONS, AND SCOPE

Although the above description contains many specificities, these should not be construed as limitations on the scope of

10 the invention but merely as illustrations of some of the presently preferred embodiments. Many other embodiments of the invention are possible. For example, the preferred embodiment is described in relation to diabetes. However, it is obvious that the system and method of the invention may be

15 used for simulating any disease which has a measurable control parameter and which requires patient self-care actions. Similarly, the self-care parameters, corresponding scaling factors, and physiological parameters described are exemplary of just one possible embodiment. Many different

20 self-care parameters, scaling factors, and physiological parameters may be used in alternative embodiments.

The preferred embodiment also presents a simulation system that includes a server, a healthcare provider computer, and

25 patient multi-media processor communicating with the provider computer via a smart card. This configuration of system components is presently preferred for ease of setting, storing, and adjusting the model parameters and scaling factors under the supervision of a healthcare provider.

30 However, those skilled in the art will recognize that many other system configurations are possible. For example, in one alternative embodiment, the system is configured as a single stand-alone computing device for executing simulations.

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In another embodiment, the smart card is eliminated from the simulation system. In this embodiment, the model parameter values and scaling factors are transmitted directly to the server from the healthcare provider computer. In a further

5   embodiment, the provider computer is also eliminated and the
    recording device is networked directly to the server. In
    this embodiment, the server is programmed to set, store, and
    adjust the model parameters and scaling factors based on
    patient data received through the recording device and
10 patient multi-media processor.

    In yet another embodiment, the server is eliminated and the
    simulation program is run on the patient multi-media
    processor. In this embodiment, the recording device and
15 multi-media processor may also be networked directly to the
    provider computer, eliminating the need for a smart card.
    Specific techniques for networking computers and recording
    devices in these alternative system configurations are well
    known in the art.
20
    Further, the first embodiment is described as a system for
    simulating a disease control parameter from simulated data
    and the second embodiment is described as a system for
    predicting a future value of a disease control parameter from
25 actual patient data. These systems are presented in separate
    embodiments for clarity of illustration and ease of
    understanding. However, it is anticipated that both
    embodiments could be combined into a single simulation system
    for simulating disease control parameter values from
30 simulated data, actual patient data, or a combination of
    simulated and actual data.

    Therefore, the scope of the invention should be determined
    not by the examples given but by the appended claims and
35 their legal equivalents.